

3

Animal Product
Manual

Reference

Organs

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Introduction

The *Organs* section covers the internal structure of animals which are imported for purpose **other than** human consumption. This includes the secretions of organs and glands. Organs and related by-products cover whole or partial animal organs and glands, and the excretions, secretions, extracts, and derivatives of organs and glands including the following:

- ◆ Bile (ox gall)
- ◆ Bone marrow
- ◆ Fat
- ◆ Gall stone (bovine)
- ◆ Gullet (goat)
- ◆ Heart
- ◆ Intestine
- ◆ Kidneys
- ◆ Lips
- ◆ Liver
- ◆ Lungs
- ◆ Musk (including grains and pods)
- ◆ Pancreas
- ◆ Parathyroid gland
- ◆ Pituitary gland
- ◆ Pyloric valve
- ◆ Rennet extract
- ◆ Spleen
- ◆ Stomach (maw)
- ◆ Thyroid gland
- ◆ Tripe
- ◆ Vell (calf)

Reference

Organs and Their Derivatives Moving Under Permit

Not covered in this section are internal animal parts such as:

- ◆ Blood imported for biological use and internal animal parts including organs and glands imported as rendered products; regulate under **Animal Waste and Related By-Products**
- ◆ Internal animal parts imported as pet food; regulate under **Pet Food, and Livestock, Poultry, and Aquaculture Feed**
- ◆ Internal animal parts imported for human consumption. May be manifested or invoiced as edible offal; regulate under **Meat and Meat Products**
- ◆ Intestines or bung caps for production of strings or glue; regulate under **Animal Waste and Related By-Products**
- ◆ Intestines or bung caps for production of casings; regulate under **Casings**



Organs, glands, and all derivatives of organs and glands of ruminant origin from countries affected with BSE are prohibited, regardless of the purpose for which they are imported.


Organs and Their Derivatives Moving Under Permit

When a VS permit authorizes entry of the organ or related by-product, match the information on the shipping documents with the information on the permit as follows:

- ◆ Current date
- ◆ Description of the material
- ◆ Shipper
- ◆ Consignee
- ◆ Conditions spelled out on the permit

Follow **Table 3-16-1** as you match the permit with the shipping documents.

TABLE 3-16-1 Action to Take When an Importation Is Authorized Entry with a VS Permit

If the shipping documents:	And the:	Then:
Match the permit		RELEASE or CONTROL as stated on the permit
Do not match the permit	Permit has expired	1. DO NOT RELEASE the HOLD 2. HAVE the consignee contact VS, TTSPS (see page 2-4-25) 3. SAFEGUARD the importation until you hear from VS, TTSPS
	Discrepancy is other than an expired permit	1. DO NOT RELEASE the HOLD 2. CONTACT PPQ-VRS-AQI or PPQ-VRS-HQ personnel for further action (see Appendix H)

Locator

When a VS permit does **not** authorize entry to organs and related by-products harvested from slaughtered animals, use [Table 3-16-2](#) which directs you to the final regulatory action.

TABLE 3-16-2 Determine Where to Find the Regulatory Action on Organs and Derivatives Not Authorized Entry by a VS Permit



If the organ or derivative is from any animal and the country of origin is:	And:	Then:
Free from BSE	Accompanied by certification of origin ¹	GO to Table 3-16-3
	Lacks certification of origin ¹	1. DO NOT RELEASE the HOLD 2. PROVIDE the importer with the appropriate options (see Table 2-2-11)
Affected with BSE		

- 1 A government certificate stating (a) the species of animal from which the material or product was derived; (b) the region or regions in which any facility where the material or product was processed is located; (c) the material or product was derived only from animals that have **never** resided in any regions listed in 9CFR 94.18 (countries/regions affected with BSE); (d) the material or product did **not** originate in, and was **never** stored, rendered, or otherwise processed in, a region listed in 9CFR 94.18; and (e) the material or product was **not** otherwise associated with a facility located in a region listed in 9CFR 94.18 nor associated with processed animal protein, offal, tankage or fat.

Reference

Organs and Their Derivatives for Research or Pharmaceutical Use

TABLE 3-16-3 Organs and Derivatives from Countries Free from BSE

If the intended use is for:	And the product is:	Then:
Animal feed or fertilizer	A rendered product	1. REGULATE as rendered products 2. GO to Animal Waste and Related By-Products
	Not a rendered product	1. REGULATE as fresh organs and glands 2. GO to Table 3-16-4
Pharmaceutical or for research		GO to Organs and Their Derivatives for Research or Pharmaceutical Use on page 3-16-4
Coagulating or curdling milk to make cheese	A rennet (includes calf vells, goat gullets, and lamb stomachs)	GO to Table 3-16-10
	Other than a rennet	1. DO NOT RELEASE the HOLD 2. CONTACT PPQ-VRS-AQI or PPQ-VRS-HQ personnel for further action (see Appendix H)
Manufacturing	Intestines or bung caps for other than casings	GO to Table 3-16-9
	Other than intestines or bung caps	
Not disclosed		1. REGULATE as fresh organs and glands 2. GO to Table 3-16-4

Organs and Their Derivatives for Research or Pharmaceutical Use

Excretions, secretions, extracts, and derivatives of organs and glands may be imported for research and pharmaceutical uses. They are usually in the form of liquids or powders. Some examples of these products follow:

- ◆ Bile
- ◆ Cholesterol
- ◆ Desiccated (dried) liver
- ◆ Enzymes
- ◆ Heparin
- ◆ Hormones
- ◆ Insulin (for research purposes only; for pharmaceutical use, see [Table 3-15-11 on page-3-15-11](#))
- ◆ Liver extract (usually in powder form)

- ◆ Oxytocin
- ◆ Pancreas powder
- ◆ Pancreatin
- ◆ Pepsin
- ◆ Thymosin
- ◆ Thyroid powder
- ◆ Trypsin

All of these products or comparable products of avian or livestock origin require a permit. Return to ***Organs and Their Derivatives Moving Under Permit*** on page 3-16-2.



Some biological products are highly perishable. Therefore, expedite an importation when you are authorized to release it. If you **cannot** release the hold, allow the importer to apply dry ice or refrigerate the by-product.

Fresh, Frozen Organs and Glands

TABLE 3-16-4 Fresh, Frozen Organs and Glands from Countries Free from BSE

If the class of animal the organ or gland is from is:	Then:
Avian (bird) or poultry	GO to Table 3-16-5
Ruminant	GO to Table 3-16-6
Swine	GO to Table 3-16-7
Neither avian, ruminant, nor swine	RELEASE

TABLE 3-16-5 Fresh, Frozen Organs and Glands of Avian Species from Countries Free from BSE


If the country of origin is known to be:	And the importation is:	Then:
Free from END	Accompanied by an official certificate of origin ¹	RELEASE
	Not accompanied by the required certification	GO to Table 3-16-8
Affected with END	—————→	

Reference

Fresh, Frozen Organs and Glands


- 1 A government certificate stating (a) the species of animal from which the material or product was derived; (b) the region or regions in which any facility where the material or product was processed is located; (c) the material or product was derived **only** from animals that have **never** resided in any regions listed in 9CFR94.18 (countries/regions affected with BSE); (d) the material or product **did not** originate in and was **never** stored, rendered, or otherwise processed in a region listed in 9CFR94.18; and (e) other material or product was **not** otherwise associate with a facility located in a region listed in 9CFR94.18 nor associated with processed animal protein, offal, tankage or fat.

TABLE 3-16-6 Fresh, Frozen Organs and Glands of Ruminants from Countries Free from BSE

If the country of origin is known to be:	And the importation is:	Then:
Free from FMD	Accompanied by an official certificate of origin ¹	RELEASE
	Not accompanied by the required certification	GO to Table 3-16-8
Affected with FMD		

- 1 A government certificate stating (a) the species of animal from which the material or product was derived; (b) the region or regions in which any facility where the material or product was processed is located; (c) the material or product was derived **only** from animals that have **never** resided in any regions listed in 9CFR94.18 (countries/regions affected with BSE); (d) the material or product **did not** originate in and was **never** stored, rendered, or otherwise processed in a region listed in 9CFR94.18; and (e) other material or product was **not** otherwise associate with a facility located in a region listed in 9CFR94.18 nor associated with processed animal protein, offal, tankage or fat.

TABLE 3-16-7 Fresh, Frozen Organs and Glands of Swine from Countries Free from BSE


If the country of origin is known to be:	And the importation is:	Then:
Free from ASF, CSF, FMD, and SVD	Accompanied by an official certificate of origin ¹	RELEASE
	Not accompanied by the required certification	GO to Table 3-16-8
Affected with ASF, CSF ² , FMD, or SVD		

- 1 A government certificate stating (a) the species of animal from which the material or product was derived; (b) the region or regions in which any facility where the material or product was processed is located; (c) the material or product was derived **only** from animals that have **never** resided in any regions listed in 9CFR94.18 (countries/regions affected with BSE); (d) the material or product **did not** originate in and was **never** stored, rendered, or otherwise processed in a region listed in 9CFR94.18; and (e) other material or product was **not** otherwise associate with a facility located in a region listed in 9CFR94.18 nor associated with processed animal protein, offal, tankage or fat.
- 2 Policy has been established for swine glands from any country affected with CSF. Contact PPQ, VRS for further action.

Shipping Requirements for Fresh, Frozen Organs and Glands from Countries with Diseases of Concern

All importations of fresh, frozen organs and glands from countries with diseases of concern must be shipped in tight, leakproof containers. A sealed, leakproof layer is placed around the absorbent material.



TABLE 3-16-8 Determine Action to Take on Fresh, Frozen Organs and Glands from Countries with Diseases of Concern

If the containers are:	And the importation is:	Then:
Not tight and leakproof		<ol style="list-style-type: none"> 1. DO NOT RELEASE the HOLD 2. CONTACT PPQ-VRS-AQI or PPQ-VRS-HQ personnel for further action (see Appendix H) 3. ALLOW the importer the opportunity to recondition 4. DO NOT RELEASE the HOLD if the importer does not recondition
Tight and leakproof	Consigned to an approved establishment	AUTHORIZE shipment under seal with VS 16-78 (see Appendix K to complete form)
	Not consigned to an approved establishment	<ol style="list-style-type: none"> 1. DO NOT RELEASE the HOLD 2. CONTACT PPQ-VRS-AQI or PPQ-VRS-HQ personnel for further action

Intestines, Bung Caps, and Other Animal Parts for Manufacturing

Moist intestines and bung caps, primarily of ruminants (sheep), are imported for manufacturing into articles such as prophylactics.

TABLE 3-16-9 Intestines, Bung Caps, and Other Animal Parts for Manufacturing from Countries Free from BSE

If the country of origin is known to be:	And the importation is:	And the importation is:	Then:
Free from FMD	Accompanied by an official certificate of origin		RELEASE
	Not accompanied by the required certification	Consigned to an approved establishment	AUTHORIZE shipment under seal with VS 16-78 (see Appendix K to complete form)
		Not consigned to an approved establishment	1. DO NOT RELEASE the HOLD 2. CONTACT PPQ-VRS-AQI or PPQ-VRS-HQ personnel for further action (see Appendix H)
Affected with FMD		Consigned to an approved establishment	AUTHORIZE shipment under seal with VS 16-78 (see Appendix K)
		Not consigned to an approved establishment	1. DO NOT RELEASE the HOLD 2. CONTACT PPQ-VRS-AQI or PPQ-VRS-HQ personnel for further action (see Appendix H)

Rennets

Rennet is the membranous lining of the fourth stomach of calves, lambs, or kids. Rennet is also a dried extract made from the stomach lining of a ruminant. To further complicate matters, there are also vegetable rennets (coagulating enzymes from plants), like thistle rennet. **Rennin** (or chymosin) is the enzyme in rennet that catalyzes the coagulation of milk in making cheese. Rennin is more commonly produced by recombinant microorganisms than from calf vells. Today, about 90% of hard cheese is made from rennin obtained from genetically modified microbes. Therefore, to regulate rennets or rennin, you must determine the source, as follows:

- ◆ Derived from a ruminant

- ◆ Derived from microbes (recombinant chymosin or rennin)
- ◆ Derived from a plant

Ruminant Derived Rennets or Rennin


The following by-products from ruminants are regulated as ruminant derived rennets:

- ◆ Calf vell
- ◆ Gullet (goat)
- ◆ Rennet extract
- ◆ Stomach

Continue to **Table 3-16-10** once you have established the source of the rennet or rennin.

Action to Take on Rennet or Rennin after Determining the Source

TABLE 3-16-10 Action to Take on Chymosin, Rennet, or Rennin

If the rennet or rennin is:	And:	Then:
Derived from a ruminant	The country of origin is affected with BSE	1. DO NOT RELEASE the HOLD 2. PROVIDE the importer with the appropriate options (see Table 2-2-11)
	The country of origin is free from BSE	GO to Table 3-16-11
Microbially produced ¹	Accompanied by a shipper's document providing the following information: ◆ Description of the product ◆ Statement that the material was produced by recombinant microbial fermentation	RELEASE
	Lacks the document or statements identified in the cell above	1. DO NOT RELEASE the HOLD 2. ALLOW the importer the opportunity to provide the required statements 3. DO NOT RELEASE the HOLD until you have the required statements
Derived from plants (bromelin, ficin, papain, or thistle rennet for example)		RELEASE

1 May be produced by fungi (*Rhizomucor meihei*, *Endothia parasitica*, or *Rhizomucor pusillus*) or genetically modified microbes (*Escherichia coli*, *Kluyveromyces lactis*, and *Aspergillus niger*).

TABLE 3-16-11 Rennets from Countries Free from BSE

If the country of origin is known to be:	And the importation:	Then:
Free from FMD	Is accompanied by a government of origin certificate	RELEASE
	Lacks the required certificate	GO to Table 3-16-12
Affected with FMD		

TABLE 3-16-12 Rennets Derived from a Country Known to Be Free from BSE, but Affected with FMD

If the importation is:	Then:
Consigned to an approved establishment	AUTHORIZE shipment under seal with VS 16-78 (see Appendix K to complete form)
Not consigned to an approved establishment	1. DO NOT RELEASE the HOLD 2. CONTACT PPQ-VRS-AQI or PPQ-VRS-HQ personnel for further action (see Appendix H)

Reference

Rennets
